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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,157

08/22/2005

Thomas Schulz

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7590

03/20/2008

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EXAMINER

LI, QIAN JANICE

ART UNIT

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1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,157	<b>Applicant(s)</b> SCHULZ ET AL.	
	<b>Examiner</b> Q. JANICE LI	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 18, 20, 24, 27, 36, 38, 40, 42 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 18, 20, 24, 27, 36, 38 and 46-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40, 42, 44, 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

The amendment and remarks filed 12/17/2007 are acknowledged. Claims 11-17, 19, 21-23, 25, 26, 29-35, 37, 39, 41, 43, and 53 have been canceled. Claims 40, 42 have been amended.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 12/17/07 response would be addressed to the extent that they apply to current rejection.

### *Election/Restrictions*

Applicant's election with traverse of Group II, claims 26, 36, 38-40, 42, and 44-53, and species election drawn to GABAnergic neurons are acknowledged. The traversal is on the ground(s) that the examination of each of the groups and species can be made without serious burden. This is not found persuasive because the inventions are distinct as indicated on record, a neural cell could be produced with different methods, and used in materially different process; and claims to the different species recite mutually exclusive characteristics of each species, such as different types of neurons and neuronal markers. These species are not obvious variants of each other based on the current record. There is an examination and search burden for these patentably distinct inventions and species due to their mutually exclusive characteristics. Each of the inventions and species requires a different field of search (e.g., searching different classifications, employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

As such, the searches for different groups and species would have certain overlap, but they are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

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Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

In the remarks, the applicant request rejoinder of claims of groups I and III.

In response, since the claims of group II are not currently allowable, it is premature to consider the request.

Claims 1-10, 18, 20, 24, 27, 36, 38, 40, 42, 44-52 are pending, however, claims 1-10, 18, 20, 24, 27, 36, 38, 46-52 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. The status of claims 36 and 38 should be corrected. Claims 40, 42, 44, 45 are under current examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 44, 45 stand rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention, for reasons of record and following.

Evidence that claims fail to correspond in scope with that which applicant(s) regard as the invention can be found in the specification, where the applicant has stated "The neural **progenitor** cells are characterized by the expression of nestin or vimentin" (Specification, paragraph 0023, emphasis added), while claim 40 states, "neural cells derived in vitro from pluripotent cells ...express one or

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more detectable markers for nestin or vimentin” and “the neural cells have the capacity to differentiate into cells of a neural lineage”. This discrepancy indicates that which cell type (i.e. differentiated neurons or neural progenitor cells) the markers belong to as described in the specification is different from what is defined in the claim(s).

In light of the state of the art, it appears claim 40 states the property of a neural progenitor cell in terms of markers expressed and the cell differentiation capability, yet claim is drawn to a differentiated neural cell. Appropriate clarification is required.

In the remarks, the applicant argues the specification teaches that the neural cells are preferably neural progenitor cells, and the term “neural cells” also includes the subgroups of differentiated and partially differentiated cells”.

In response, as such, the claimed neural cells would include neural progenitors, partially differentiated and subgroups of differentiated cells; and the culture composition could only be homogeneous in the sense the cells in it are all neural lineage. The claims are vague and indefinite because it is unclear when the amended claim 40 recites “a predominantly homogeneous population of human neural cells”, what cell type it refers to, and which subgroup neural cell it encompasses, and hence the metes and bounds of the claim are uncertain.

Claim 40 is vague and indefinite, because of the claim recitation, “predominantly homogeneous”. The word homogeneous means being the same throughout, whereas predominant means most common.

Further, the phrase “predominantly homogeneous” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree of the homogeneous, and thus one of the skills in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 42, 44, 45 stand rejected under 35 U.S.C. 102(a) as being anticipated by *Carpenter et al* (Exp Neurol 2001;172;383-97, IDS).

*Carpenter et al* teach a cell culture composition comprising a population of human cells derived *in vitro* from embryonic stem cells (e.g. fig. 2A), comprising various types of neural cells including those expressing nestin (e.g. fig. 2B), and capable of differentiation into cells of a neuron cell, preferably a GABAergic neuron phenotype (e.g. fig. 3C, 7D, 7I). *Carpenter et al* go on to teach the hES cells were cultured in the absence or presence of RA. When the RA was absent, 56 +14% of cells expressing PS-NCAM, a neural progenitor cell marker, whereas 65 + 9% cells expressed A2B5, an oligodendrocyte precursor cell marker; while in the presence of RA in the ES cell culture, 87+9% cells were positive for A2B5 or PS-NCAM (paragraph bridging page 388-9, and fig. 2N). *Carpenter et al* also teach that astrocytes (cells expressing GFAP) could be obtained from the culture (fig. 7C, H). Since these are all neural cells based on the definition of the specification, having the characteristics required by the claims, the culture disclosed by *Carpenter et al* meets claim limitation, and instant claims embrace

the cells taught by *Carpenter et al.* Accordingly, *Carpenter et al* anticipate instant claims.

In the remark, the applicant argues *Carpenter* teach a mixed population of cells.

The applicant also argues that the culture method of *Carpenter et al* resulted nestin-positive neural precursors and other progenitor cell markers, but not markers for mature cells.

In response, as an initial matter, nestin positive is required by claim 40.

As to mature or precursor cell, it is noted upon instant amendment and clarification by the applicant under 35 USC § 112, 2<sup>nd</sup> paragraph, the claim does not appear to be drawn to mature neural cell only. This is because claim 40 requires the neural cells having the capacity of further differentiation, this is not the characteristic of mature neural cells.

As such, the culture taught by *Carpenter et al* comprises cells as required by instant claims, i.e. highly homogeneous neural cells express one or more detectable marker such as nestin, the claims do not exclude A2B5 or PS-NCAM positive cells. To the contrary, claims require the neural cells to have the traits of precursor cells, i.e. capable of differentiating into neurons, and oligodendrocytes. Since the A2B5 is a marker for progenitors of oligodendrocytes, PS-NCAM is a marker for progenitors of neurons, the claimed neural cells should bear these markers.

The applicant then argues that the neural cells taught by *Carpenter et al* only able to differentiate a small percentage of the cells into mature cells of a neural lineage. In response, the claims require the claimed composition comprising neural cells, but do

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not require the percentage of mature cells the neural cell could differentiate to, so as long as the cells are neural cells, capable of differentiate into the three lineages, they meet claim limitation.

Accordingly, the rejection stands.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 42, 44, 45 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-52 of copending Application No. 10/539,951. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both drawn to a neural cell.



This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7:30 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI, M.D./*  
*Primary Examiner, Art Unit 1633*

Q. Janice Li, M.D.  
Primary Examiner  
Art Unit 1633

*QJL*

March 26, 2008